

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Yoshitake <i>et al.</i>	Confirmation No.: 2325
Appl. No.: 10/594,436	Art Unit: 1611
35 U.S.C. § 371 Date: September 26, 2006	
U.S. Nat'l. Ph. of PCT/JP2005/005217	Examiner: Kevin S. Orwig
I.A. Fd: March 23, 2005	
For: Controlled-Release Pharmaceutical Composition and Method for Producing the Same	Atty. Docket: 1089.0670000/MAC

**Tenth Supplemental Information Disclosure Statement  
Under 37 C.F.R. § 1.97(b)**

*Mail Stop Amendment*

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms PTO/SB/08A equivalent and PTO/SB/08B equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. § 1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Copies of documents **FP1** and **NPL1-NPL7** are submitted.

Examiner's attention is directed to an error in a previous citation. Specifically, on the 3<sup>rd</sup> supplemental IDS filed October 17, 2007, the second citation in "other document" is incorrect (the citation that begins FDA/Center for Drug Evaluation and Research's

Orange Book listing for ACIPHEx). The citation currently says, "showing use since August 19, 1998." The citation should say "showing use since August 19, 1999."

Examiner's attention is also drawn to the prosecution history of US Appl. Nos. 11/543,991 and 10/849,544 in which, *inter alia*, the Examiner is also citing JP-2000-128779 against the claims of those applications.

Examiner's attention is also drawn to the prosecution history of US Appl. Nos. 11/543,991 and 12/088,080 in which, *inter alia*, the Examiner is also citing Aoki US 2005-0163846 (corresponding to WO 03/043661) against the claims of those applications.

Examiner's attention is also drawn to the prosecution history of US Appl. No. 12/443,804, the file history of which had been previously brought to Examiner's attention in the pleading of the 6<sup>th</sup> supplemental IDS filed October 6, 2009.

As the file histories of each of U.S. Application Nos. 10/849,544, 11/543,991, 12/088,080 and 12/443,804 are available in the Image file Wrapper system, copies are not provided herewith to avoid duplicating copies. Applicants would be pleased to submit paper copies of each of the file histories for Examiner's review if Examiner prefers.

Documents **NPL1** and **NPL2** are the ISR and IPRP for PCT/JP2006/319147, which is believed to correspond to US Appl. No. 12/088,080, which published as US 2009-0148519 A1, which has previously been made of record in the 6th supplemental IDS filed October 6, 2009.

Documents **NPL3** and **NPL4** are the ISR and IPRP for PCT/IB2007/004315, which published as WO 2008/062320, a copy of which is submitted herewith as **FP1**.

Documents **NPL5** is the IPRP for PCT/JP2005/005217, which is believed to correspond to US Appl. No. 10/594,436, which published as US 2008-0095839 A1, which has previously been made of record in the 6th supplemental IDS filed October 6, 2009. The ISR has previously been made of record with the filing of the original IDS on September 26, 2006.

Documents **NPL6** and **NPL7** are the ISR and IPER for PCT/JP2002/012132, which is believed to correspond to US Appl. No. 10/849,544, which published as US 2005-0163846 A1, which has previously been made of record in the 1st supplemental IDS filed January 17, 2007 (and Form 892 as attached to the Office action of March 18, 2009).

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing of an Office action after the filing of a Request for Continued Examination. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

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Date: May 17, 2011

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